International Standard

ISO 14644-15

Cleanrooms and associated controlled environments —

Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration

Salles propres et environnements maîtrisés apparentés —

Partie 15: Évaluation de l'aptitude à l'emploi des équipements et des matériaux par la détermination de la concentration chimique aéroportée

Second edition
2026-05

Reference number
ISO 14644-15:2026(en)

© ISO 2026



COPYRIGHT PROTECTED DOCUMENT

© ISO 2026

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Symbols ... **4**

5 Test setup ... **4**
5.1 General ... 4
5.2 Closed design ... 5
5.3 Closed design special application ... 6
5.4 Open design ... 7

6 Representative mode ... **7**
6.1 Equipment ... 7
6.2 Material ... 7

7 Visual inspection ... **8**
7.1 General ... 8
7.2 Equipment ... 8
7.3 Material ... 8

8 Test description ... **9**

9 Calculation of the measured concentrations ... **9**

10 Calculation of specific emission rate ... **10**
10.1 Calculation of specific emission rate — Closed design ... 10
10.2 Calculation of specific emission rate — Open design ... 10

11 Assessment ... **11**
11.1 General ... 11
11.2 Required input data ... 11
11.3 Calculation to determine the effect on a cleanroom or controlled zone ... 12
11.4 Assessment of the suitability of material(s) or equipment for an existing cleanroom or controlled zone ... 12

12 Documentation ... **12**
12.1 General ... 12
12.2 Common documentation requirements ... 13
12.3 Test documentation ... 13
12.4 Visual inspection ... 13
12.4.1 Equipment ... 13
12.4.2 Materials ... 13

Annex A (informative) **Example calculation for suitability assessment of one equipment (existing installation)** ... **14**

Annex B (informative) **Example calculation for suitability assessment of wall material (existing cleanroom/clean zone installation)** ... **16**

Annex C (informative) **Suitability assessment of a combination of equipment and floor material in a cleanroom to be designed** ... **17**

Bibliography ... **19**

© ISO 2026 – All rights reserved

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 243, *Cleanroom technology*,in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 14644-15:2017), of which it constitutes a minor revision. The changes are as follows:

— term class (classification, classified) changed to level or assessment where appropriate and Introduction reworded to accommodate the change;

— phrase “has to be” changed to “shall be”;

— updated ‘document titles’ and ‘Source’ dates where appropriate;

— removed references not mentioned in the text from the bibliography;

— minor editorial changes.

A list of all parts in the ISO 14644 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© ISO 2026 – All rights reserved

Introduction

Cleanrooms and associated controlled environments provide for the control of contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in industries such as aerospace, microelectronics, optics, nuclear, and life sciences (pharmaceuticals, medical devices, food, healthcare).

The assessment of suitability of equipment for use in cleanrooms and associated controlled environments is related to the assessment of air cleanliness for chemical contamination. Examples and suitability assessments are given in Annexes A, B and C.

© ISO 2026 – All rights reserved

Cleanrooms and associated controlled environments —

Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration

1 Scope

This document specifies requirements and guidelines for assessing the chemical airborne cleanliness of equipment and materials which are foreseen to be used in cleanrooms and associated controlled environments that are linked to the ISO standard for air cleanliness by chemical concentration (see ISO 14644-8).

This document does not apply to the following:

— health and safety requirements;

— compatibility with cleaning agents and techniques;

— cleanability;

— biocontamination;

— specific requirements of equipment and materials for processes and products;

— design details of equipment.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14644-8:2022, *Cleanrooms and associated controlled environments — Part 8: Assessment of air cleanliness by chemical concentration (ACC)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

© ISO 2026 – All rights reserved